U.S. PATENT & TRADEMARK OFFICE
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Attorney Docket No. 54275.8004.US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Examiner: Dr. Jeffery Parkin
Anna P. CATANIA and James M. LIPTON	Group Art Unit: 1648
Serial No.: 09/533,341	
Filed: March 23, 2000	
For: **Antimicrobial and Anti-Inflammatory Peptides for Use in Human Immunodeficiency Virus**	

AFFIDAVIT OF JAMES M. LIPTON

PURSUANT TO 37 C.F.R. § 1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, James M. Lipton, Ph.D., hereby declare, subject to penalty of perjury, as follows:

1. I am currently the Chief Scientific Officer of Zengen, Inc. and have been involved in research on neuroscience, physiology and peptide chemistry for 39 years; I obtained a Ph.D. in Neuroscience from the University of Colorado in Boulder, Colorado in 1964. I have published no less than 200 research papers in well-known scientific journals and am credited with two United States Patents.

2. I have reviewed United States Patent Application Serial No. 09/533,341 entitled "ANTIMICROBIAL AND ANTI-INFLAMMATORY PEPTIDES FOR USE IN

HUMAN IMMUNODEFICIENCY VIRUS (the '341 Application).

3. I am an inventor of the invention disclosed in the '341 Application.

4. I have read and understood the Office Action dated 3/19/03 regarding the '341 Application. The Office Action maintains rejections of claims directed to microbes distinct from *Staphylococcus aureus* and *Candida albicans* as these two organisms are the only microbes specifically tested in the '341 Application. The Office Action maintains the rejections under 35 U.S.C. § 112, first paragraph, and asserts that: "Specifically, the disclosure appears to demonstrate that KPV displays antibacterial activity toward two particular organisms, *Staphylococcus aureus* and *Candida albicans*...However, the claims are broadly directed toward treatment of any given condition and the inhibition of any given pathogen. The specification fails to provide adequate support for this claim language."

5. Regarding the second issue raised in the Office Action, support in the specification may be found for inhibition of any pathogen at pages 16, 18, and 25-30. As an example, where penicillin is directed to the bacterial wall of certain pathogens, it is not effective against bacteria without a cell wall. KPV works by a far more primitive system, a system included within nearly all living organisms. For HIV, this support can be found on page 16 and is based on the intracellular reduction of NF-κB activation. Because NF-κB is a central mediator in cytokine activation of HIV transcription, altering its function, via KPV, causes decreased replication of HIV. (Further support on page 18.)

6. As to opportunistic or 2° infections, the killing of the broad scope of pathogens is accomplished through the intracellular cAMP accumulation in the pathogen when treated with KPV. This is discussed at pages 25-30. cAMP is a common component of living cells. This is a fact known in the art. Since all microbial agents contain cAMP, it is within the scope of the application as disclosed to include microbes of a broader scope by showing that bacteria as in *Staphylococcus aureus* and yeast or fungi as in *Candida albicans* have been affected negatively in their growth by use of KPV. Figure 14 and 15 are also instructive on this mechanism of action. Thus, the application supports a cross phyla efficacy for the KPV tripeptide.

7. I hereby further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true and, further, that these statements are made with knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of United States Patent Application Serial No. 09/781,046 and United States Patent Application Serial No. 09/573,861, any patent issuing thereon, or any patent to which this verified statement is directed.

Executed on August 13, 2003, at Woodland Hills, California.

By: _____
James M. Lipton, Ph.D.